Discussion Questions – All Panel Members

- What's the timeframe for NGS to be used routinely for TB screening and TB diagnostics?

- Will NGS technology alone be sensitive and specific enough to detect antimicrobial drug resistance, especially in minor variants, and be used as an aid for patient management? What is the feasibility of NGS as a tool for AMR monitoring before prescribing certain drugs to patients?

- What is the role and trust of AMR information in open-access genomic databases for NGS TB screening and NGS TB diagnostic efforts? What controls would be expected and how would it be regulated/enforced?

- Will in silico regulatory data sets that challenge NGS platforms be sufficient to determine performance? Should these data sets be tailored to pick up low prevalence variants in mixed infections?

Discussion Questions

For industry:

- Based on the presentations, what challenges does industry see on the regulatory and policy front?

For policy makers/regulators:

- Why is process for the development WHO policy guidance for TB diagnostics different from the WHO pre-qualification process for other IVDs? Can the WHO provide specifics on policy directions regarding NGS endorsement for monitoring TB drug resistance?
- Is the document that EUCAST released being considered for EU regulation of NGS?
- Can the FDA provide additional guidance regarding use of NGS to monitor drug resistance, specifically for TB disease?
- Is the FDA considering modular regulation similar to what happened in the human sequencing space?
- When/how will mutation scoring algorithms for genotypic drug susceptibility testing be regulated? How can such algorithms be regulated in light of the ever evolving field that is understanding the clinical significance of mutations with TB.